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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|-------------|----------------------|---------------------|------------------|
| 10/705,660 | 11/10/2003 | Terry L. Bowersock | 28341/6127NDIV1 | 6143 |
| 4743 | 7590 | 11/08/2005 | EXAMINER | |
| MARSHALL, GERSTEIN & BORUN LLP 233 S. WACKER DRIVE, SUITE 6300 SEARS TOWER CHICAGO, IL 60606 | | | KIM, YUNSOO | |
| | | | ART UNIT | PAPER NUMBER |
| | | | 1644 | |

DATE MAILED: 11/08/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/705,660

Applicant(s)

BOWERSOCK ET AL.

Examiner

Yunsoo Kim

Art Unit

1644

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 September 2005.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-34 and 43-78 is/are pending in the application.
- 4a) Of the above claim(s) 6-10, 31-34, 50-53, 74 and 75 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-5, 11-30, 43-49, 54-73 and 76-78 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date <u>2/9/04, 6/13/05</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Claims 1-34 and 43-78 are pending.

2. Applicants' election of species without traverse of items (i) and (ii) read on methylcellulose and polyoxyethylene surfactants drawn to claims 1-5, 11-30, 43-49, 54-73 and 76-78 in the reply filed on 9/22/05 is acknowledged. Upon consideration of applicants' remark, the election of species set forth on items (iii) and (iv) drawn to adjuvant and cations has been removed.

Accordingly, claims 6-10, 31-34, 50-53, 74 and 75 are withdrawn from the consideration by the examiner 37 CFR.1.142(b) as being drawn to a nonelected species.

Claims 1-5, 11-30, 43-49, 54-73 and 76-78 read on elected species are under consideration in the instant application.

3. Applicants' claim for domestic priority under 35.U.S.C. 119(e) is acknowledged.

4. Applicants' IDS filed on 2/9/04 and 6/13/05 have been acknowledged. However, the submission of international search report on IDS filed on 6/13/05 is acknowledged, however, these references have been crossed out as they are not appropriate for IDS.

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 29, 30, 44-49, 54-73 and 76-78 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A) HLB recited in claims 29, 30, 72 and 73 needs to be defined.

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B) The phrase "said cations" recited in claim 44 (and dependent claims thereof) has insufficient antecedent basis.

C) The phrase "a composition" recited in claim 44 (and dependent claims thereof) needs to be differentiated (vaccine composition or surfactant composition).

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

8. Claims 1-5, 14-28, 43-49, 57-71, 77 and 78 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Pat. No. 5,674,495 (IDS reference) in view of Jackson Thesis (IDS reference, 1995) and U.S.Pat. 4,792,452.

The '495 patent teaches a method of vaccinating a vertebrate species by an oral administration of alginate composition comprising antigen (i.e. bacteria or virus, col. 4, lines 22-24), antigen in solution and/or oil (col. 7, lines 30-33), crosslink alginate particles with calcium chloride (col. 5, lines 40-48), coating the alginate composition with poly-lysine (col. 7, lines 35-40, Example 1, Example 6), the alginate particle size should be 1-10 microns (col. 5, lines 7-10), further addition of stabilizer (col. 3, lines 10-15) and cholera toxin as potential adjuvant (i.e. col. 2, lines 58-63, col. 3-4 overlapping paragraph).

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The '495 patent further teaches some developmental problems in oral vaccine including stability or adsorption of antigenic composition and targeted or controlled delivery (col. 2, lines 56-63).

The patentability of a product does not depend on its method of production. Claims 15-18 and 58-61 are included in this rejection as crosslinking of the alginate particle is part of a process of making. Claims 20 and 63 are also included in this rejection as the surfactant composition in (A)(e)(i) encompasses other surfactants in view of Jackson.

The '495 patent does not teach the alcohol ethoxylate (polyethylene surfactant, i.e. BRIJ 93) and cellulose ether (methylcellulose, i.e. METHOCEL).

However, Jackson teaches BRIJ 93 adds stability to alginate emulsion composition (p. 103, 106, 126, 155-160) and the short polyethylene oxide chains do not produce sufficient steric stabilization and prevent alginate droplet coalescence (p. 156).

The '452 patent teaches the use of METHOCEL in combination with the alginate in order to provide pH independent sustained released product in drug delivery (col. 1, lines 24-30, 43-58, col. 3, lines 45-56, Examples 1-8, claims 1 and 20). The composition comprising METHOCEL and alginate promotes proper release rate (col. 3-4 overlapping paragraph) independent of pH of the environment (claim 1).

Therefore, one of the ordinary skill in the art would have been motivated to combine METHOCEL taught by the '452 patent and BRIJ 93 taught by Jackson in the oral alginate vaccine composition taught by the '495 patent because BRIJ 93 would add stability to alginate vaccine composition and METHOCEL promotes controlled release of vaccine composition in the digestive tract of low pH and prevents limited adsorption due to degradation of antigenic composition in the digestive tract.

From the teachings of references, it would have been obvious to one of the ordinary skill in art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was prima facie obvious to one of the ordinary skill in the art at the time of invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

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9. Claims 1, 2, 4, 11-19, 21-30, 43, 44, 54-62, 64, 71-73, 76 and 78 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Pat. No. 5,674,495 (IDS reference) in view of Jackson Thesis (IDS reference, 1995) and U.S.Pat. 5,019,100.

The teachings of the '495 patent and Jackson have been discussed, supra.

The patentability of a product does not depend on its method of production. The claims 15-18 and 58-61 are included in this rejection as crosslinking of the alginate particle is part of a process of making.

The '495 patent or Jackson does not teach the poly(ethylene oxide)-poly(propylene oxide)-poly(ethylene oxide) (PEO-PPO-PEO) tri-block copolymer (i.e., PLURONIC L61).

As evidenced in the specification of instant application, p. 14, PLURONIC L 61 is a preferred surfactant.

However, the '100 patent teaches PLURONIC L61 or F68 in combination with hydrogel (i.e. alginate, the '495 patent categorizes alginate in hydrophillic matrices, col. 3, lines 55-65) preparation used as matrices for the regulated release of drugs (col. 1, lines 29-51). The PLURONIC L 61 has formula of $(\text{PEO})_3-(\text{PPO})_{30}-(\text{PEO})_3$. Thus, HLB being 8.3 is expected property of PLURONIC L 61.

Therefore, one of the ordinary skill in the art would have been motivated to combine PLURONIC L61 taught by the '100 patent and BRIJ 93 taught by Jackson in the oral alginate vaccine composition taught by the '495 patent because BRIJ 93 would add stability to alginate vaccine composition and PLURONIC L61 provide matrices for the regulated release of drugs. The resulted alginate/surfactant formulation will provide more controlled delivery of antigenic formulation.

From the teachings of references, it would have been obvious to one of the ordinary skill in art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was prima facie obvious to one of the ordinary skill in the art at the time of invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

10. No claims are allowable.

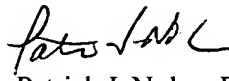
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11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Yunsoo Kim whose telephone number is 571-272-3176. The examiner can normally be reached on Monday thru Friday 8:30 - 5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on 571-272-0841. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Yunsoo Kim
Patent Examiner
Technology Center 1600
October 31, 2005


Patrick J. Nolan, Ph.D.
Primary Examiner
Technology Center 1600